Volume 13 • Number 6 • 2010
VALUE IN HEALTH

The Cost-Effectiveness of Spinal Cord Stimulation for Complex Regional Pain Syndrome

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ABSTRACT

Objectives: Health-care policymakers and payers require cost-effectiveness evidence to inform their treatment funding decisions. The aims of this study were to assess the cost-effectiveness of the addition of spinal cord stimulation (SCS) compared with conventional management alone (CMM) in patients with complex regional pain syndrome (CRPS), and to determine the cost-effectiveness of nonrechargeable versus rechargeable SCS implanted pulse generators (IPGs).

Methods: A decision analytic model was used to synthesize data on CRPS patient outcomes and health-care costs over a 15-year time horizon from the perspective of the UK National Health Services. Data were sourced from two SCS randomized controlled trials. Results are expressed as an incremental cost per quality-adjusted life-year (QALY) in 2008 GBP.

Results: The incremental cost-effectiveness of SCS compared with CMM was £3562 per QALY, a finding that was robust across sensitivity analyses with an 87% probability that SCS is cost-effective at a willingness to pay threshold of £30,000. When the longevity of an IPG is 4 years or less, a rechargeable (and initially more expensive) IPG is more cost-effective than a nonrechargeable IPG.

Conclusions: In selected patients with CRPS, SCS is cost-effective as an adjunct to CMM. Despite their initial increased expense, rechargeable IPGs should be considered when IPG longevity is likely to be short. These findings support policymakers to extend the use of SCS as a good value for money treatment for CRPS.

Keywords: complex regional pain syndrome, cost utility analysis, cost-effectiveness, decision analytic modeling.

Introduction

The pathophysiology of complex regional pain syndrome type I (CRPS I) is unknown, although the condition appears to be associated with minor trauma. CRPS I is characterized by ongoing pain, allodynia, functional impairment, abnormal sweating, and abnormal vascular reactivity [1]. The syndrome is associated with significant morbidity, reduced functional ability, and reduced health-related quality of life [2,3]. CRPS I has an estimated incidence of 5.46 per 100,000 and prevalence 20.57 per 100,000 [2].

Various strategies have been used to reduce pain intensity in CRPS, including conventional pain medication, physical therapy, sympathetic blocks, and transcutaneous electrical nerve stimulation, but largely with poor results [4].

Spinal cord stimulation has been used since 1967. Currently, it is used to treat patients with intractable pain syndromes, including CRPS [5]. The precise mechanism of pain modulation is not fully understood. One theory is that it involves direct and indirect inhibition of pain signal transmission, and to have autonomic effects, the technique may inhibit chronic pain by stimulating large diameter afferent nerve fibers in the spinal cord. Pain is masked by the production of numbness/tingling (paresthesia).

In a randomized controlled trial (RCT) that assessed SCS and conventional medical management (CMM) versus CMM alone in CRPS I, a significant benefit was demonstrated in patients receiving SCS [6]. The results showed that at 6 months and 2-years follow-up, SCS reduced pain and improved health-related quality of life [6,7]. Although the benefits of SCS diminished with time, at 5-years follow-up, patients with a SCS implant continued to show improved pain relief compared with patients receiving CMM alone [8].

In addition to evidence for a clinical benefit, health policymakers and payers increasingly request evidence of value for money when making funding decisions [9,10]. In October 2008, the United Kingdom's (UK) National Institute of Health and Clinical Excellence (NICE) analyzed the cost-effectiveness of SCS and recommended that the UK National Health Service (NHS) should offer the treatment to selected CRPS patients [11].

In this article, we update the NICE cost-effectiveness analysis and also explore the cost-effectiveness of nonrechargeable versus rechargeable SCS implanted pulse generators (IPGs).

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10.1111/j.1524-4733.2010.00744.x

Methods

We used an economic model to compare the cost-effectiveness of the addition of SCS to CMM versus CMM alone. The analysis was conducted from the perspective of the UK NHS.

Study Population

The model simulated a population of male and females patients with CRPS I aged 18 to 65 years who fulfilled the diagnostic criteria described by the International Association for the Study of Pain [12], and as described by Kemler et al. [6]. The study population had impaired function and symptoms beyond the trauma, with the pain syndrome that affected one entire foot or one entire hand for at least 6 months; patients had failed to achieve a sustained response to conventional pain medication, physical therapy, sympathetic blockade, or transcutaneous nerve electrical stimulation, and had a pain intensity of at least 5 cm on a visual-analogue scale (VAS) from 0 mm (no pain) to 100 mm (very severe pain). Patients are excluded if they suffer from

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Raynaud's disease, neurological abnormalities not related to CRPS, other conditions affecting the function of the qualifying extremity, a blood-clotting disorder or use of a pacemaker.

Model Structure

A two-stage decision analytic model was developed in Microsoft EXCEL from a previously published model [13]. A decision tree (Fig. 1) reflected possible initial 6-month responses to SCS [6], and a Markov model simulated costs and quality-adjusted life-years (QALYs) over a 15-year time horizon, which is within the range of long-term observational SCS data [14].

In the decision tree, patients allocated to SCS first underwent a screening trial (patients eligible for SCS undergo a "screening trial" where a percutaneous implantation is performed). In the Kemler trial, 66.7% of screened patients achieved optimal pain relief and therefore received a permanent implant, with the rest receiving CMM (See Fig. 1) [6].

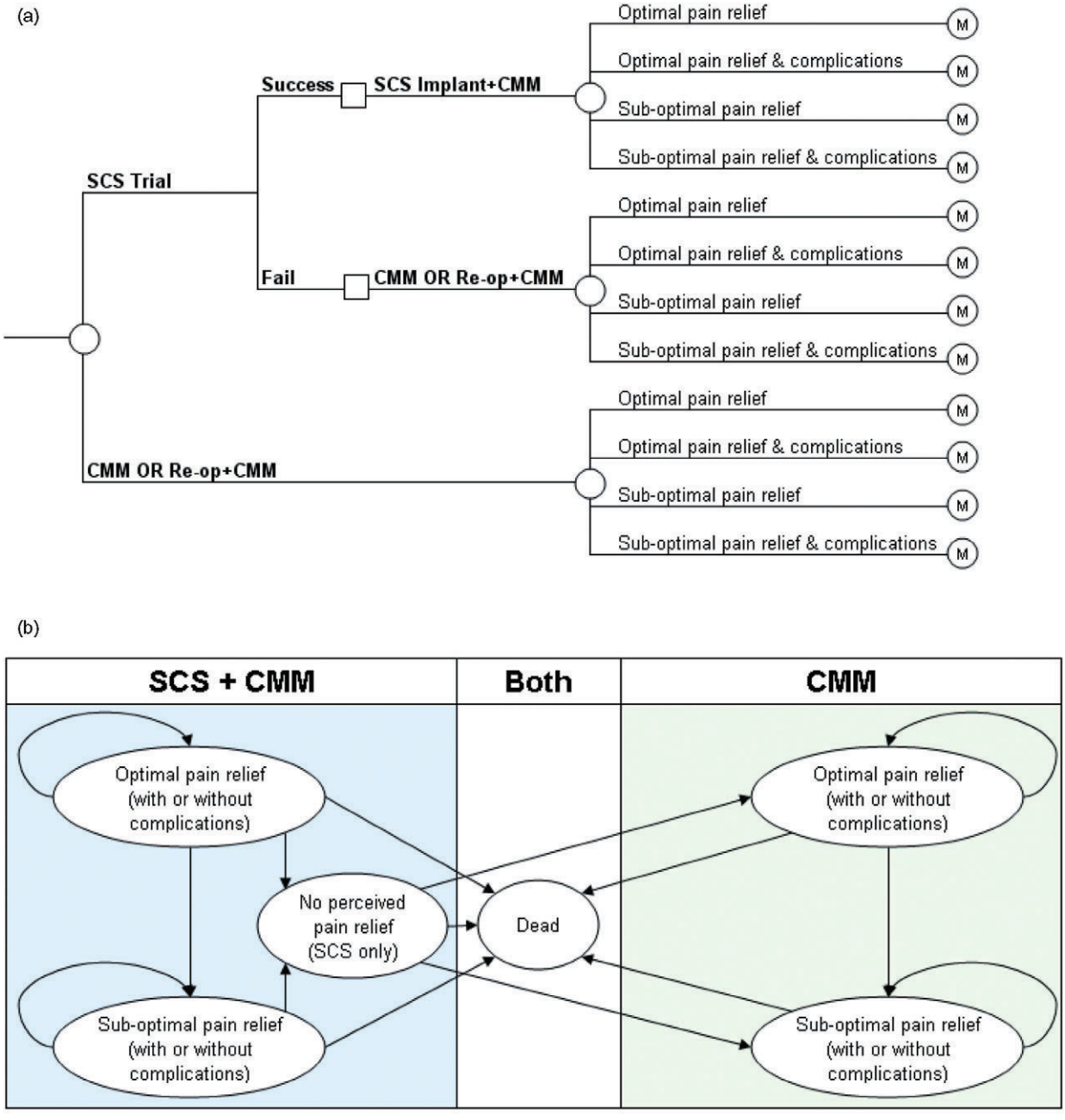

Figure 1 Two-stage model representations: (a) Six-month decision tree. Note: optimal pain relief is defined as ≥50% reduction from baseline. (b) Long-term Markov model. Note: Economic evaluations assume that the therapy being evaluated (e.g., SCS) is not available to patients in the CMM arm, hence, no patient in the comparator arm can receive SCS in this model. Optimal pain relief is defined as ≥50% reduction in perceived pain relief from baseline. SCS, spinal cord stimulation; CMM, conservative medical management; Reop, reoperation; M, Markov model.

Patients could experience one of six mutually exclusive health states: optimal pain relief (at least 50% reduction in pain VAS from baseline) with or without complications, suboptimal pain relief (less than 50% reduction in pain VAS but more than zero) with or without complications, no pain relief, or death.

During each subsequent 3-month Markov cycle, patients allocated to SCS were assumed to remain in their health state unless they: 1) experienced a complication; 2) moved from optimal to sub-optimal pain relief; 3) moved to no pain relief (and switched to CMM or reoperation); or 4) died. Cycle length was chosen to represent a clinically meaningful time interval.

Table 1a,b show the values assigned to each model probability, utility, and cost.

Pain Relief and Complications

The primary clinical outcome in the model was the achievement of at least a 50% reduction in pain VAS compared with baseline. We used the 6-month results of the RCT of Kemler as the source of data [6]. In addition to the published findings, we were able to access the detailed patient level data from this trial. For patients who continued to benefit from SCS after six months, we estimated the annual probability of losing pain relief (and switching treatment) to be 3.24% [14].

Short-term SCS complication rates were sourced from the Kemler trial, in which 25% of patients receiving an IPG experienced a complication requiring intervention within the first six months [6]. The 5-year follow-up data for the Kemler trial was used to calculate the long-term (6 months or more post-implantation) SCS complications rate of 12.5% per annum.[8] No complications related to CMM treatment were reported by Kemler et al. [6–8].

Health-Related Quality of Life

Utility values for health states were based on responses to the EuroQoL/EQ-5D questionnaire directly collected in the Kemler trial at 6-months follow-up and using UK population weights [15]. This yielded mean utility values of 0.195 for no pain relief, 0.581 for optimal pain relief. It was assumed that in patients with optimal pain relief that a SCS complication had a negative impact on utility, causing a disutility of –0.05 (Table 1b) [13].

Measuring and Valuing Health-Care Resource Use

Although costs of SCS and CMM were assessed in the Kemler trial based on the level of health-care utilization, there are two limitations with using these data in this analysis: 1) the assessment of health-care utilization was limited to particular categories (e.g., drug medication was not recorded), and 2) fixed unit cost ("tariff") for all patients were applied (e.g., the cost of SCS screening was constant for all patients). Therefore, we sourced costs from the PROCESS study, an international multicentre trial that randomized failed back surgery syndrome (FBSS) patients to receive either SCS and CMM or CMM [16]. The PROCESS study undertook a detailed "bottom up" assessment of the level of health utilization for each SCS and CMM patient [17]. Based on a UK health-care perspective, we applied unit costs from relevant sources and published estimates (Table 1b) (NHS England, 2005–06; to each category of health-care utilization. Results are reported in GBP sterling.

At 2008 prices provided by Medtronic, Inc., the cost of a nonrechargeable IPG was £7761 (Synergy, Medtronic, Inc., Minneapolis, MN, USA), and a replacement unit was £7177. The nonrechargeable IPG system cost £9762, and a replacement system cost £9085 (see Table 1b). The rechargeable IPG system (Restore Ultra, Medtronic, Inc.) cost £15,076, and a replacement system cost £12,860. The Kemler trial reported that the IPG would remain in situ for an average of approximately 4 years, after which a replacement will be necessary [8].

At 2008 prices provided by Medtronic, Inc., a nonrechargeable IPG costs £7761 (Synergy), and its replacement costs £7177. We compared a rechargeable IPG system (Restore Ultra, with a cost of £15,076 and £12,860 for replacements and longevity of 9 years) with the nonrechargeable IPG system described earlier.

We discounted costs and QALYs at an annual rate of 3.5% [18].

Cost-Effectiveness Reporting and Sensitivity Analyses

We conducted probabilistic sensitivity analysis (PSA) to account for underlying parameter uncertainty (in a PSA, each parameter is given a probability distribution, and uncertainty in all model parameters is then explored simultaneously using 1000 Monte Carlo simulation). The variables in the PSA included clinical success, resource use, complication rate, and SCS failure rate over time. We presented the results as cost-effectiveness acceptability curves [19], and judged them to be cost-effective on the basis of maximum willingness to pay thresholds of £20,000 and £30,000 per QALY [20].

To examine the impact of uncertainty on cost-effectiveness in the model inputs, we performed one-way sensitivity analyses by changing the base-case value of each model input parameter to its upper and lower limits (see Table 1a,b) while holding all other values constant. To identify the variables with greatest impact, we plotted the results of the one-way sensitivity analyses in a tornado diagram (See Fig. 2).

We separately examined the cost-effectiveness of use of a rechargeable IPG (with an assumed longevity of 9 years compared with a non-rechargeable IPG). This analysis is presented on the net benefit scale, that is, the maximum willingness to pay threshold minus the incremental cost-effectiveness. A net benefit of zero or higher was considered to demonstrate cost-effectiveness of a nonrechargeable SCS device compared with a rechargeable device, and a negative net benefit indicated the opposite.

Results

Base-Case Analysis

Over the 15-year time period of the model, patients receiving SCS accrued costs of £86,770 (Table 2). By comparison, a patient receiving CMM alone accrued costs of £79,775, a difference of £6994. This difference in cost is driven by the additional cost of the SCS system (£9762) and any replacement IPGs necessary (£7177 for a replacement unit).

Over the lifespan of the model, the SCS arm accrued an additional 1.96 QALYs per patient compared with CMM alone, resulting in an incremental cost-effectiveness ratio of £3562 per QALY.

Sensitivity Analyses

One-way sensitivity analyses identified four variables that had the greatest impact on the cost-effectiveness of SCS. The cost-effectiveness of SCS increases as: 1) the cost of adjunct drug pain therapy for SCS patients decreases; 2) time before a replacement IPG is needed increases; 3) the cost of drug therapy in CMM patients increases; and 4) the annual probability of no pain relief with SCS decreases (Fig. 2). The fact that the incremental cost-

Table 1 (a) Summary model inputs—values and sources; (b) Summary of utilities and unit costs—values and sources

(a)

Model parameter	Base-case value	Source	Sensitivity analysis range*	Distribution	Source
Probability of receiving SCS after trial screening					
SCS + CMM vs. CMM	0.667	Kemler et al. (2000) [6]	0.513–0.821	Beta	95% CI
SCS + CMM vs. CMM					
Probability of successfully screened patient achieving optimal pain relief following SCS + CMM	0.792	Kemler et al. (2000/2004/2008) [6–8]	0.629–0.954	Beta	95% CI
Probability achieving optimal pain relief following CMM	0.056	Kemler et al. (2000/2004/2008) [6–8]	0.000–0.161	Beta	95% CI
Probability of complications with CMM	0.000	Kemler et al. (2000) [6]	0.000–0.000	Beta	95% CI
Probability of patient receiving a surgical revision achieving optimal pain relief	0.188	Kemler et al. (2000/2004/2008) [6–8]	0.000–0.379	Beta	95% CI
Probability of complication with SCS requiring intervention in first 6 months	0.250	Kemler et al. (2000/2004/2008) [6–8]	0.077–0.423	Beta	95% CI
Annual probability of complication in first year of subsequent SCS implants	0.417	Kemler et al. (2000/2004/2008) [6–8]	0.219–0.614	Beta	95% CI
Annual probability of complication with SCS after 6 months	0.125	Kemler et al. (2000/2004/2008) [6–8]	0.066–0.184	Beta	95% CI
Decrement in annual probability of achieving optimal or suboptimal pain relief with SCS + CMM after 6 months	0.0324	Kumar et al. (2006) [14]	0.00–0.1577	Beta	Min and max
Annual probability of death	0.0092	UK Office National Statistics [26]	0.0090–0.0094	Beta	±10%
Longevity of IPG (nonrechargeable)	4 years	Kemler at al. 2000/2004/2008 [6–8]	2–10	Gamma	Expert opinion

(b)

Parameter	Base-case value	Source	Sensitivity analysis range†	Distribution	Source
Utility					
Optimal pain	0.581	Kemler et al. (2000/2004/2008) [6–8]	0.548–0.612	Beta	Minimum and maximum
Suboptimal pain	0.195	Kemler et al. (2000/2004/2008) [6–8]	0.212–0.329	Beta	Minimum and maximum
SCS failure (no perceived pain relief)	0.168	Kemler et al. (2000, 2004, 2008) [6–8]	0.151–0.185	Beta	Minimum and maximum
SCS complication	–0.05	Taylor and Taylor (2005) [13]	–0.10–0.00	Beta	Expert opinion
SCS IPG costs					
Screening for SCS	£4069	Manca et al. (2008) [17]	£2245–£6984	Gamma	Minimum and maximum
Failed screening	£1800	Manca et al. (2008) [17]	£775–£3022	Gamma	Minimum and maximum
SCS IPG implantation	£9762	Manca [17] and Medtronic Inc‡	£9554–£14,900	Gamma	Minimum and maximum
SCS IPG reimplantation	£9085	Manca [17] and Medtronic Inc§	£7166–£11,890	Gamma	Minimum and maximum
SCS IPG explantation	£1800	Manca et al. (2008) [17]	£0–£2536	Gamma	Minimum and maximum
SCS IPG-related complication	£622	Manca et al. (2008) [17]	£203–£1572	Gamma	Minimum and maximum
Drug treatment for pain cost					
SCS + CMM	£1692	Manca et al. (2008) [17]‖	£0–£4493	Gamma	Minimum and maximum
CMM	£2664	Manca et al. (2008) [17]‖	£0–£7075	Gamma	Minimum and maximum
Non drug treatment for pain cost					
SCS + CMM	£28	Manca et al. (2008) [17]‖	£0–£34	Gamma	Minimum and maximum
CMM	£804	Manca et al. (2008) [17]‖	£0–£973	Gamma	Minimum and maximum

*Range of parameter values used in probabilistic sensitivity analysis.
†Range of parameter values used in probabilistic sensitivity analysis.
‡System cost of £7761.
§IPG cost of £7177.
‖Costs for 6-month period, subsequently annualized for the model.
CMM, conservative medical management; IPG, implanted pulse generator; QALY, quality-adjusted life-year; SCS, spinal cord stimulation.

effectiveness of SCS remained below the threshold of £20,000 per QALY across all the ranges of one-way sensitivity analyses supports the robustness of the base-case analysis. There was also evidence that SCS could be economically dominant (i.e., more QALYs at lower costs) compared with CMM if the cost of adjunct pain therapy for SCS patients is less than £1197 per patient, the time before a replacement IPG is 7 years or more, or the cost of drug therapy in CMM patients is higher than £4645 per patient.

Probabilistic sensitivity analysis (PSA) was also performed in which each model parameter was varied around its mean using appropriate distributions (see Table 1a,b). The results of the PSA

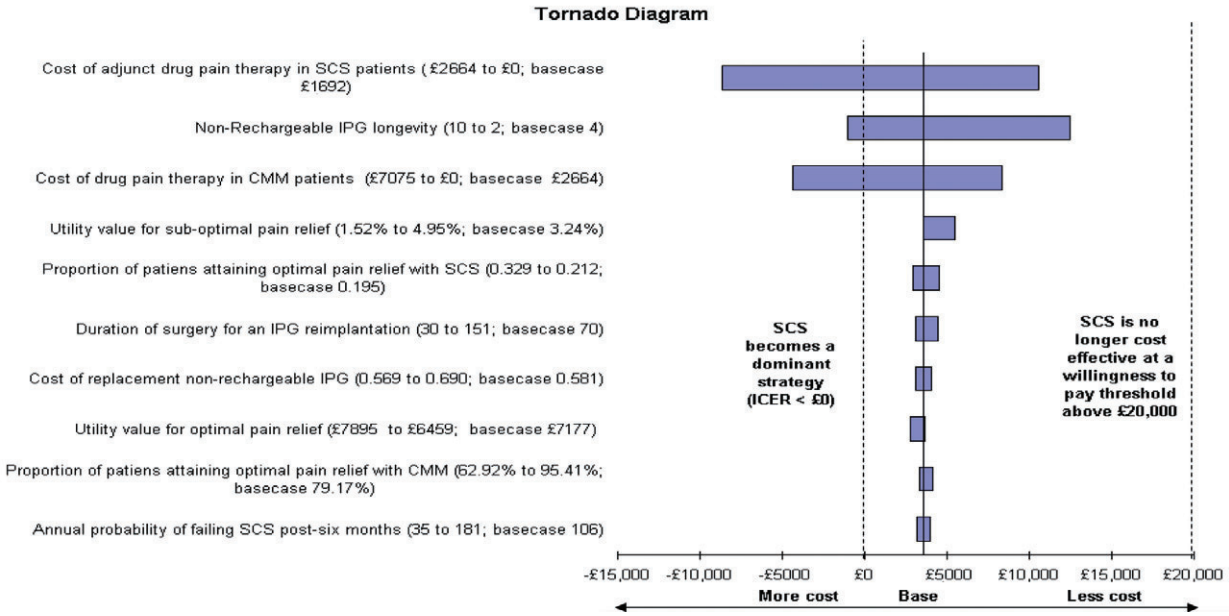

Figure 2 Incremental cost-effectiveness analysis—one-way sensitivity analyses. The intersections of the solid vertical lines with the *x*-axes represent incremental cost-effectiveness per quality-adjusted life-year (ICER). The horizontal bars show the impact of varying the base-case value of various model parameters to their upper and lower limits (see Tables 1 and 2) while holding all other values constant. A lower value than the base-case assumption demonstrates that SCS is more cost-effective versus CMM. A higher value than the base-case assumption indicates that CMM is more cost-effective than SCS. SCS, spinal cord stimulation; CMM, conservative medical management.

demonstrate that with a willingness to pay threshold of £20,000 per QALY, there is a 74% probability that SCS is cost-effective increasing to an 87% probability when this threshold increases to £30,000 per QALY (see Fig. 3).

Rechargeable Versus non-Rechargeable IPGs

In this analysis, it was assumed that the rechargeable IPG had a fixed battery life of 9 years, while nonrechargeable IPG longevity was allowed to vary from 1 to 16 years. All other parameters were the same for the two IPG systems. As shown in Figure 4, rechargeable IPGs lasting 9 years are cost-effective at a threshold of £20,000 per QALY, where the expected longevity of a non-rechargeable IPG is less than 4 years (Fig. 4).

Discussion

Our model-based analysis shows that SCS is a cost-effective addition to CMM in the treatment of CRPS I. The incremental cost-effectiveness ratio for SCS relative to CMM alone falls below the maximum willingness to pay threshold of £20,000 to £30,000 per QALY used by policymakers in UK and many developed health-care economies [20].

Table 2 Base-case incremental cost-effectiveness of SCS

	SCS	CMM	Difference
Total cost/patient	£86,770	£79,775	£6,994
QALYs/patient	4.84	2.88	1.96
Incremental cost per QALY		£3,562	

Note: Costs and QALYs discounted at 3.5% per annum, where £1.00 = US$ 1.62.
CMM, conservative medical management; QALY, quality-adjusted life-year; SCS, spinal cord stimulation.

This finding that SCS is cost-effective concurs with the one previous economic evaluation of SCS in CRPS. Kemler and Furnée in a trial-based analysis reported an incremental cost-effectiveness ratio for SCS compared with CMM of €22,583 per QALY (at 1998 prices) [21]. While still below the maximum willingness threshold reported above, the higher incremental cost-effectiveness ratio is reflective of the 1 year time horizon and therefore the much-smaller QALY gain with SCS (+0.18 QALYs) compared with that seen in the present study at 15 years (+1.96 QALYs). Modeling trial data over the remaining average of 41 years of life-expectancy of patients, Kemler and Furnée reported SCS to be economically dominant, that is, lower costs and higher QALYs compared with CMM. Given the absence of published long-term follow-up data, we truncated our model extrapolation at 15 years. Nevertheless, we were able to demonstrate in some scenarios (longer IPG longevity and lower CMM costs) that SCS was economically dominant compared with CMM.

Our incremental cost ratio for SCS relative to CMM was lower than seen in the original assessment by NICE (£25,096 per QALY) [22]. As part of the present analysis, we had access to the individual patient data for the RCT of SCS for CRPS [6], and therefore, we were able to direct estimate the proportion of CMM-treated patients who achieved 50% of more pain relief (i.e., 1 out of 18 patients, 5.6%). In the original NICE assessment, this proportion was assumed to much higher (44%), resulting in a smaller incremental QALY gain for SCS compared with CMM (+0.35 QALYs) compared with the present analysis (+1.96 QALYs). Given the incremental costs were similar (NICE assessment: +£8775 vs. current analysis: +£8365), the incremental cost-effectiveness was lower in the present analysis.

As expected, we found that if the longevity of the nonrechargeable SCS IPG extends beyond the base-case assumption of 4 years, for the same IPG cost, the cost-effectiveness of SCS becomes increasingly favorable. Conversely, if the stimulation

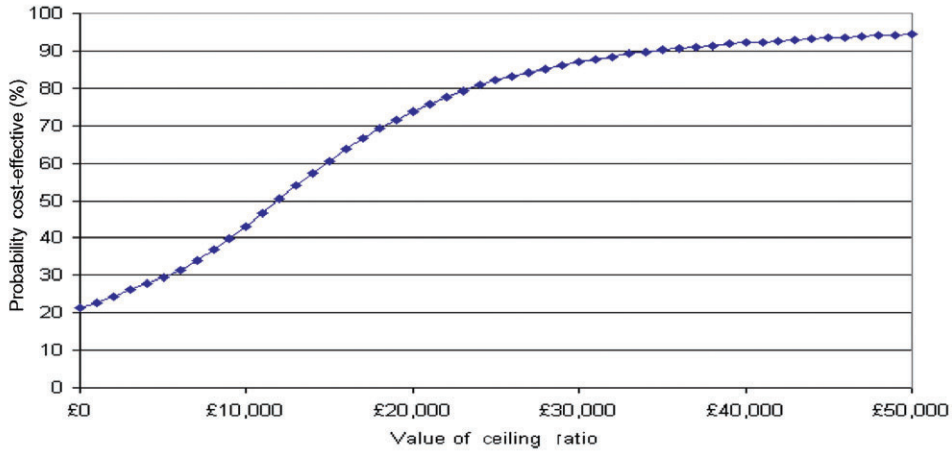

Figure 3 Cost-effectiveness acceptability curve. Illustrates the probability that SCS is cost-effective compared with CMM at differing maximal cost-effectiveness ratio ceilings. SCS, spinal cord stimulation; CMM, conservative medical management.

requirements of a patient reduce the longevity of the IPG below 4 years, we found an initially more expensive rechargeable SCS IPG becomes more cost-effective than a nonrechargeable IPG. The model-based analysis by Hornberger showed that the use of a rechargeable SCS IPG (assuming 10–25 years longevity) was cost-saving compared with a nonrechargeable IPG over the patient lifetime [23]. Nevertheless, in contrast to this cost-consequence analysis, we have shown that the economic advantage of rechargeable systems is limited to those CRPS patients who are likely to have a short IPG longevity.

Strengths and Limitations

This study has several strengths. We used outcome and health-care utilization data from RCTs [6,7] and a systematic review of long-term observational follow-up of SCS [23]. We considered long-term costs and outcomes, including the cost and clinical impact of IPG-related complications and routine IPG replacement. Long-term complications were sourced from the recent long-term follow-up results of the Kemler RCT. We also comprehensively reflected uncertainty in model inputs. In contrast with previous model-based analyses of SCS [13], our analysis uses EQ-5D-based utility scores directly reported by CRPS patients [21].

Our study also has potential limitations. First, given the lack of detailed patient level health-care utilization data available from the Kemler RCT, we instead sourced health-care costs from the PROCESS trial [15]. Although the PROCESS trial was undertaken in FBSS rather than CRPS patients, we believe that this source of cost data has a number of strengths in the context of this study—it is a large, multicenter RCT in SCS, and provides data from 12 centers in Canada, Europe, Australia, and Israel [14]; it is based on a detailed assessment of the health-care utilization in individual SCS and CMM patients over a 6-month follow-up period [15]. Also, current guidelines indicate that the breadth of drug and nondrug therapy received by patients in the PROCESS is reflective

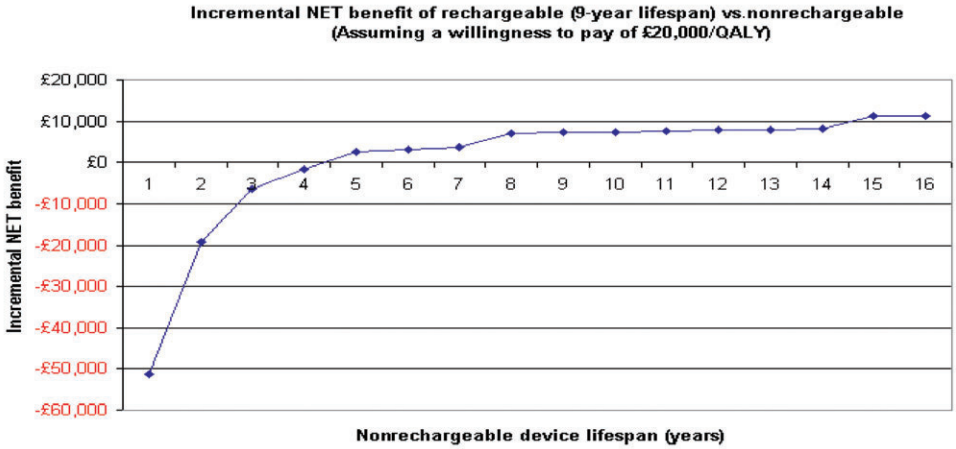

Figure 4 The cost-effectiveness of a rechargeable (9-year lifespan) versus nonchargeable. IPG across differing nonrechargeable IPG lifetimes (assuming a maximum willingness to pay of £20,000/QALY). A net benefit of zero or higher demonstrates that the nonrechargeable IPG is cost-effective compared with the rechargeable IPG, while a negative net benefit indicates that the rechargeable IPG is more cost-effective than a nonrechargeable IPG. IPG, implanted pulse generator; QALY, quality-adjusted life-year.

of the pattern of care recommended for CRPS patients [5]. Second, we did not have direct estimates of the disutility of complications (associated with either SCS or CMM) from the Kemler RCT 6–8. In accord with usual trial methodology, health-related quality of life was assessed in this study at fixed follow-up points rather than at the time a complication occurred [13]. We applied both a cost and disutility when a patient experienced a SCS-associated complication. Nevertheless, for the purposes of modeling cost-effectiveness, we made the conservative assumption of no disutility or cost to be associated with these CMM-related events. In the PROCESS trial, 4% of SCS patients and 23% of CMM patients reported drug-related adverse events over a 12-month period [16]. No CMM-related adverse events were reported in Kemler trial 6–8. Finally, the time horizon of our model is 15 years, while the duration of the disease process is likely to be the patient's life expectancy. Given the lack of robust outcome data on SCS cohorts beyond 15 years, however, we were reluctant to extrapolate costs and outcomes beyond this time.

Implications for Policy and Future Research

The cost-effectiveness findings of this study support the widespread use of SCS for CRPS as an alternative to CMM alone and underscore the 2008 NICE recommendation that SCS be offered to adults with CRPS who experience chronic pain (measuring at least 50 mm on a 0–100 VAS for at least 6 months) despite appropriate CMM [11].

The potential population "need" for SCS in most countries is uncertain [24]. Nonetheless, according to the Hospital Episode Statistics, 32% of the estimated 639 patients who receive a SCS implant in England in 2006 are patients with CRPS [25]. Assuming a 5% annual growth, we project the cost of treating CRPS in England to increase from £1.9 million to £2.3 million over a 5-year period.

In undertaking this analysis, we identified a number of areas where further evidence collection would be particularly beneficial. First, given the rate of SCS success is inversely related to the duration of chronic pain [14], a clinical trial and economic evaluation are needed to examine the impact of moving SCS to a position early in the treatment continuum for CRPS. Second, SCS implant registries should be used to confirm projected rechargeable longevity estimates derived from battery decay algorithms and to track patient outcomes. Finally, studies are needed to assess the health-related quality of life impact of SCS-related complications and drug-related adverse events.

Conclusions

In selected CRPS patients, SCS is a cost-effective option as an adjunct to CMM with an incremental cost-effectiveness ratio below the willingness to pay threshold of £20,000 to £30,000 per QALY. When the longevity of an IPG is less than 4 years, a rechargeable (and initially more expensive) IPG is the most cost-effective option. These findings support the increased use of SCS in the management of CRPS.

Source of financial support: This study was sponsored by Medtronic, Inc. The planning, conduct and conclusions of this report are those of the authors and not the company. The publication of study results was not contingent on the sponsor's approval or censorship of the article.

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